

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

NIVAGEN, INC.,

Plaintiff

v.

SUN PHARMACEUTICALS INDUSTRIES,
INC.

Defendant.

Case No.: 2:24-cv-36-RWS-RSP

JURY TRIAL DEMANDED

**SUN PHARMACEUTICAL INDUSTRIES, INC.’S MOTION FOR ISSUANCE OF
LETTERS OF REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE**

Defendant Sun Pharmaceutical Industries, Inc. (“Sun”) respectfully requests that this Court issue Requests for Judicial Assistance (“Letters Rogatory”) pursuant to the Hague Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters in the form attached hereto as **Exhibit 1**. Sun submits this Application pursuant to the Hague Convention, 28 U.S.C. § 1781, and Rules 28(b) and 34(c) of the Federal Rules of Civil Procedure. The assistance requested is for the Appropriate Judicial Authority of the United Kingdom to compel the production of relevant documents from Pharmanovia regarding its phenobarbital sodium drug Gardenal®.

Additionally, Sun seeks discovery from Nobelpharma Co. Ltd. (“Nobelpharma”), a Japanese entity, regarding its phenobarbital sodium drug Nobelbar®. While Japan is not a member of the Hague Convention on Taking Evidence Abroad in Civil or Commercial Matters, Sun submits this application for the issuance of Letters Rogatory pursuant to the laws of Japan governing international discovery requests and the customs of obtaining international judicial assistance in the absence of a treaty or other agreement attached hereto as **Exhibit 2**.

I. BACKGROUND

This is a patent infringement case involving U.S. Patent Nos. 11,406,598 (“the ’598 patent”) and 11,878,076 (“the ’076 patent”) (collectively, “the Asserted Patents”). Plaintiff Nivagen, Inc. (“Nivagen”) has alleged, among other things, that Sun makes, sells, advertises, offers for sale, and/or uses a phenobarbital sodium drug product that purportedly infringes the Asserted Patents in the United States. Dkt. 1 at ¶39.

Sun believes that Pharmanovia and Nobelpharma both possess critical information regarding prior art to the Asserted Patents. Pharmanovia is an entity located in the United Kingdom and has acquired the rights to Gardenal[®], a phenobarbital sodium intravenous drug approved for the use and sale in France. Nobelpharma is a Japanese entity that developed, sought regulatory approval for, manufactures, and markets its lyophilized phenobarbital sodium intravenous drug Nobelbar[®].

Therefore, Sun submits this application for international judicial assistance as to Pharmanovia through the Appropriate Judicial Authority of the United Kingdom (Exhibit 1) and to Nobelpharma through the Appropriate Judicial Authority of Japan (Exhibit 2).

II. ARGUMENT

This Application, in part, is made pursuant to, and in conformity with the Hague Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters. T.I.A.S. No. 7444; 23 U.S.T. 2555, reprinted following 28 U.S.C. § 1781. The Hague Convention provides that “[i]n civil or commercial matters a judicial authority of a Contracting State may, in accordance with the provision of law of that State, request the competent authority of another Contracting State, by means of a Letter of Request, to obtain evidence, or to perform

some other judicial act.” T.I.A.S. No. 7444. Both the United States and the United Kingdom are parties to the Hague Convention.

A formal Letter of Request addressed to the Central Authority of the United Kingdom, signed and sealed by this Court, is necessary under the Hague Convention to order the production of documents by an entity that is not a party to this litigation. *See* T.I.A.S. No. 7444; 23 U.S.T. 2555. Pharmanovia is based in Essex, the United Kingdom, and is within the jurisdiction of the Central Authority for the United Kingdom.

Additionally, while Japan is not a member of the Hague Convention on Taking Evidence Abroad in Civil or Commercial Matters, Sun appropriately moves for international judicial assistance in the form of letters rogatory to the appropriate judicial authority of Japan to seek discovery from Nobelpharma, a Japanese entity.

Sun seeks documents from Pharmanovia relating to information regarding the development, drug approval process, and/or market authorization for the drug Gardenal[®]. Sun additionally seeks documents and testimony from Nobelpharma relating to information regarding the development and/or new drug approval process for its drug Nobelbar[®]. This information will inform the inherent properties of the drugs that are prior art to the Asserted Patents, including documentation on manufacturing processes, stability, impurities, and other drug characteristics. The documents and testimony sought by Sun are relevant to its defenses in this litigation, including the validity of the Asserted Patents.

Sun has no other means to obtain the documents and testimony sought in the attached requests. For this reason, Sun respectfully requests that the Court grant this Application.

III. RELIEF REQUESTED

Requests pursuant to the Hague Convention are transmitted directly to the receiving state. *See* <https://www.hcch.net/en/states/authorities/details3/?aid=526>. Accordingly, Sun respectfully requests that the Court return (1) the original copy of the signed, sealed, and issued Letters Rogatory (Exhibit 2), and (2) two certified copies, to the undersigned counsel. The letter will be transmitted to the UK central authority by Sun's counsel, with the Court's permission.

In the absence of a controlling treaty or agreement, the transmission of letters rogatory must be facilitated by the U.S. Department of State. *See* <https://travel.state.gov/content/travel/en/legal/travel-legal-considerations/international-judicial-assistance/obtaining-evidence/Preparation-Letters-Rogatory.html>. Accordingly, Sun respectfully requests the Court return (1) the original copy of the signed, sealed, and issued Letters Rogatory (Exhibit 2), and (2) two certified copies, to the undersigned counsel. The United States Department of State will oversee transmission of the Letters Rogatory to Japan through diplomatic channels as provided in 28 U.S.C. § 1781(a)(2). Sun will reimburse this Court for any expenses incurred in connection with the issuance and return of the Letters Rogatory.

Respectfully submitted,

Date: October 22, 2024

s/ *Justin T. Oakland*

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Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that counsel of record who are deemed to have consented to electronic service are being served this 22nd day of October, 2024, with a copy of this document via the Court's CM/ECF system.

s/ Justin T. Oakland
Justin T. Oakland

CERTIFICATE OF CONFERENCE

The undersigned hereby certifies that counsel for Defendant conferred with counsel for Plaintiff. Counsel for Plaintiff indicated that it is unopposed to this motion.

s/ Justin T. Oakland
Justin T. Oakland